Remarks

Claims 68-74, 76-119, 122-127, 129 and 132-138 are pending in the above-identified patent application. With this Response, new claims 139 and 140 are added. Applicants submit that the claim amendments are fully supported by the application as originally filed and do not present new matter. See, for example, page 20, lines 9-14 of the application. In addition, claim 126 has been amended to eliminate the extra comma. Upon entry of the current amendments, claims 68-74, 76-119, 122-127, 129 and 132-140 will be pending and in front of the examiner for consideration. Applicants respectfully request reconsideration and further examination of the application in view of the amendments above and remarks below.

Specification Objection

The Office objected to the specification as assertedly failing to provide proper antecedent basis for the claimed subject matter by failing to disclose the body member comprising a tube in a coil or zig-zag shape along its entire length from its proximal end to its distal end.

The objection is traversed. The application describes embodiments wherein the body member comprises a tube in a coil or zig-zag shape along its entire length from its proximal end to its distal end, and therefore provides proper antecedent basis for the claimed subject matter.

For example, page 9, lines 3-6 states:

Further, the coil shape of the body member allows the device to be screwed or twisted into the eye through an incision approximately the same size as the outer diameter of the tube forming the body member 2. (underlining our emphasis)

As another example, page 12, lines 14-20 states:

In one embodiment, as shown in FIGS. 2a-4c and 5a-5c, the non-linear body member 2 is fabricated of a tube that is wound into a coiled shape. As shown in the Figures, the tube forming the non-linear body member 2 is preferably cylindrical in shape, with a circular cross-section. However, the shape of the tube is not limited and, for example, may alternatively have square, rectangular, octagonal or other cross-sectional shapes. Preferably, the tube has a lumen 10 extending along its length for housing the substance to be delivered. (underlining our emphasis)

Since embodiments are described (and illustrated in the referenced figures) wherein the entire body member from its proximal to distal end can be fabricated from a tube, the claimed subject matter has proper antecedent basis in the specification. Withdrawal of the objection is respectfully requested.

35 U.S.C. § 103 –Weiner and Rosenman

The Office rejected claims 68-74, 76-91, 93-97, 99-109, 111-119, 122-127, 129 and 132-138 under 35 U.S.C. 103(a) as assertedly being unpatentable over Weiner *et al.*(U.S. Patent No. 5,466,233; herein "Weiner") in view of Rosenman *et al.* (U.S. Patent No. 6,478,776; herein " Rosenman").

The rejection is traversed.

The Office asserts that:

"Weiner teaches an ocular drug delivery device having a non-linear shaped body member (12, 14a)..." and,

"With respect to claims 69-71, the device body member comprises at least five deviations from a linear path as seen by the multiple surfaces of the body member."

The Office's assertions that Weiner teaches a non-linear body member are not correct. Device embodiments (figures 1-5) described Weiner have a linear path, but there is no teaching or suggestion of a body member having a non-linear path. Non-parallel surfaces 70 of Weiner's cone-shaped cap (figure 1) and rounded ends 26 of the test tube-shaped embodiments (figures 2-5) do not amount to non-linear shaped body members as claimed. As understood by the application, a non-linear body member deviates from a linear path (see, for example, page 7, lines 21-26), such as a coil shape. To understand if a body member is linear or non-linear one must follow the "longitudinal axis" of the device (col. 5, line 35 of Weiner refers to longitudinal axis), not a device surface. The longitudinal axes of Weiner's tack embodiments are linear, not non-linear.

Weiner does not provide sufficient motivation to modify the shape of its shape or its body member from linear to non-linear. Rather, according to Weiner, there are reasons why one of skill would *not* have wanted to change the linear body member to a

non-linear configuration as claimed. One reason is because Weiner teaches that a linear body member allows for a substantially straight insertion and this is preferred.

> *In the preferred method of insertion, the tack 10 of the present invention is inserted into the eye 18 by injection. While the tack 10 may be inserted by hand into the sclera 24, injection is preferred as it helps to prevent risk of accidental damage or abrasion to the scleral surface 28. In addition, injection provides for a substantially straight insertion. As shown in FIG. 15, the tack 10 may be injected by loading the tack 10, with the first end 22, 26 of the post 12 pointed toward a first end 84 of the syringe 82 and the head 16 abutting the plunger 86 of the syringe 82 when the plunger is in a fully extended position. (underlining our emphasis)*

On the other hand, the non-linear configuration of the claimed device generally uses an insertion process with a turning motion, such as a rotating or screwing motion, to provide for insertion of the device. One of skill at the time of the invention would not have modified the Weiner device in a way that would require deviation from its preferred substantially straight insertion.

As discussed in Applicant's previous response, the current invention solves problems with the prior art implants. For example, prior art ocular implants are limited in amount of drug that can be housed within and delivered to the eye. In efforts to overcome drug delivery problems, Applicants have determined that longer implants can obstruct vision, and wider implants can be more uncomfortable. Applicants' claimed ocular drug delivery device is capable of holding greater amounts of drug per unit length, and also provides a configuration that aids in preventing unwanted ejection from the eye.

New claims 139 and 140, recite a cross sectional diameter of the body member of 0.5 mm or less, and a diameter in the range of 0.25 mm to 0.5 mm, respectively. Weiner does not teach or suggest a cross sectional diameter in these ranges. Rather, Weiner suggests a diameter between 1 mm and 4 mm, and to reduce the cross-sectional diameter would considerably limit the amount of drug that could be placed in Weiner's device. Within the context of Weiner's teaching, modification of its device towards the claimed subject matter would not have made sense.

The eye is a very unique area of the body and presents distinct challenges for the delivery of bioactive agents to its tissue, and in particular to the inner portion of the eye.

Many of the complexities of ocular drug delivery are described in Applicants' background section, for example, see page 1, lines 18-30. Given the unique properties of the eye, one of skill in the art of ocular drug delivery would not have looked towards devices designed for other areas of the body in attempts to address unique challenges associated with ocular drug delivery.

The Office has cited the teaching of Rosenman as being relevant to the claimed subject matter. However, Rosenman is in a dissimilar area of medical treatment as it is directed to the treatment of heart tissue. Because of the fundamentally different anatomic concerns between the eye and the heart, Weiner and Rosenman cannot be considered to be in the same field of endeavor. Further, one of skill in the art of ocular drug delivery as discussed in the current application would be, for example, an ophthalmologist, who is a doctor having at least post-graduate training in ophthalmology. An ophthalmologist does not practice cardiothoracic surgery, nor would have been expected to have been familiar with particular cardiovascular technologies, such as described by Rosenman.

The Office has asserted (page 6 of the Office action):

> "*Rosenman disclose implanting the device within the heart and other organs of the body which can include the eye.*"

In response, Rosenman does not teach or suggest inserting its device in the eye. Rosenman discusses devices and methods for the treatment of heart disease. At the time of the invention and absent an impermissible hindsight reconstruction of the claimed subject matter, one of skill in the art of ocular drug delivery would not see the teaching of Rosenman as suitable for treatment of an ocular condition.

Figure 3 of Rosenman shows an implant delivery catheter 7 with outer sheath 13 that slides over an inner core 14 and the tip of the device in distal tip area 10 (col. 6, lines 11-13). Rosenman's figure 2 shows the patient's heart with distal end 10 of the implant delivery catheter 7 and the distal end 11 of the guide catheter 3 within the left ventricle chamber. Rosenman discusses at col. 11, lines 38-47, an implantation procedure for the fixation coil, which first inserts the implant delivery catheter into the patient's vasculature through the skin, typically entering the femoral artery through the thigh, and navigates the catheter into the heart. Therefore, the "incision" (skin) that is made during the

surgical process of Rosenman must be large enough to allow entry of the diameter of the catheter shaft into the body (see Rosenman's figures 2, 4, and 21). The Office asserts (on page 5) that Rosenman's device:

"*abuts an incision through which the device is inserted to stabilize the device.*"

This is incorrect. Rosenman's implant does not abut the skin incision made during the insertion process. At the site of implantation in the cardiac tissue, Rosenman does not make an incision. Rather, Rosenman teaches that a centrally located hollow straight needle 18 is extended through the central axis of the helices and penetrates the myocardium when the helices are screwed in (column 7, lines 3-6). Further, as discussed in the Applicants' response of June 22, 2010, Rosenman's implant is entirely surrounded/buried within the solid tissues of the heart, and therefore any portion of its implant can provide stabilization in the surrounding solid tissue. Again, there are fundamental anatomical differences between the heart and eye, and one of skill at the time of the invention in view of the cited art would not have understood that an implantable ocular device could be stabilized in a material that is mainly fluid (vitreous), with solid tissue (including sclera) only at the outer surface without the disclosure of the Applicants' invention.

The particular problem that is of concern to Rosenman is fundamentally different than issues addressed by the current invention. As a problem to be solved, Rosenman proposes the devices and methods as an alternative to solid particles which can escape into the arterial blood stream and be pumped out to the body. Rosenman states: "Therefore, there is a need for a structure that can deliver solid or degradable forms of therapeutics to a depth of the myocardium while lowering the risk for embolic events." See, col. 3, lines 51-64. Delivering drug to the myocardium and lowering the risk for embolic events are not problems to be solved according to the current technology. In reference to *In re Oetiker*, 977 F.2d 1443 24 USPQ2d 1443 (Fed. Cir. 1992), if the prior art reference is not in the Applicants' field of endeavor, it must be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. Because Rosenman is directed to the

treatment of heart tissue it is not considered in the Applicants area of endeavor, and further Rosenman is not reasonably pertinent to the particular problem with which the Applicants were concerned.

The rejection does not meet other required criteria. Because an obviousness rejection has to be supported with an articulated reasoning with rational underpinning (MPEP 2143.01 IV) the reason for combining references or modifying their teaching needs to clear on its face, not confusing, and technically sound.

> *A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR, 550 U.S. at 398 (U.S. 2007), 82 USPQ2d at 1396 quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).*

The Office asserts that it would have been obvious to modify Weiner's device to change its described post shape into a coil or zig-zag shape as described by Rosenman because:

"...the coil shape allows the drug to be released in all directions." (pages 7, 8, and 9)

According to this statement, the Office apparently believes that drug is not capable of being released from Weiner's device "in all directions," and that modification of Weiner's device to a non-linear configuration would allow this to happen. Respectfully, this asserted reasoning is confusing to the Applicants and not believed to be technically sound. In Weiner's device, drug released from the post should diffuse in all directions in the vitreous because the vitreous has fluid-like properties. On the other hand, the Rosenman device is surrounded by solid myocardial tissue, which is fundamentally different than vitreal fluid. The Office's argument that *"...the coil shape allows the drug to be released in all directions,"* is not believed to sufficiently support an articulated reasoning with rational underpinning as required by MPEP 2143.01 IV.

Applicants maintain that there is no teaching, suggestion, or motivation by either Weiner or Rosenman or any other cited documents that an ocular implant could or should be designed with a coil or zig-zag shape along its body length (which resides in fluid). Applicants assert that for at least the reasons discussed herein, one could not have arrived at the claimed subject matter at the time of the invention in view of Weiner and Rosenman. Withdrawal of the rejection is respectfully requested.

35 U.S.C. § 103 – Weiner, Rosenman, and Johnson

The Office rejected claims 92, 98 and 110 under 35 U.S.C. 103(a) as assertedly being unpatentable over Wiener *et al.* in view of Rosenman *et al.* as applied to claims 83, 93 and 99 above, and further in view of Johnson (U.S. Patent No. 5,972,027; herein "Johnson"). Withdrawal of the rejection is respectfully requested.

As discussed above, Weiner and Rosenman fail to teach or suggest Applicants' devices or methods as recited in independent claims 83, 93, and 99. Johnson is cited for allegedly describing shape memory materials. However, Johnson does not remedy the above-noted deficiencies in Weiner and Rosenman. Accordingly, claims 92, 98 and 110 (which depend from claims 83, 93, and 99) are patentable over Weiner and Rosenman and Johnson.

Conclusion

It is respectfully submitted that this communication is fully responsive to the current non-final Office Action. The Examiner is invited to telephone the undersigned in the event that such communication is deemed to expedite prosecution of this application.

Respectfully Submitted,

Date: December 16, 2010

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